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NOVACOR

4, passage Saint Antoine
92508 Rueil Malmaison Cedex 08
France
Tel : +33 1 41 39 01 61
Fax : +33 1 41 39 01 99

JAN 1 9 2005

510(k) SUMMARY of SAFETY & EFFECTIVENESS

Submitter :
NOVACOR France
4, Passage Saint Antoine
92508 Rueil Malmaison cedex – France

Phone : 00 33 1 41 39 05 78
Fax : 00 33 1 41 39 01 99
E-mail : dgrenier@novacor.fr

Contact person : Mrs. Dominique GRENIER – Regulatory Affairs Director

Device trade name : VISTA PLUS HOLTER RECORDER

Common/Usual name: Ambulatory ECG Holter Recorder

Classification name : Electrocardiograph, Ambulatory with analysis algorithm.

Predicate devices :
Spiderview – ELA MEDICAL Inc. – K032466
Cardio ID+(RZ153+) – ROZINN ELECTRONICS Inc. – K022540
Digitrak Plus – BRAEMER CORP – K993617

Device description :
The VISTA PLUS holter recorder is a miniature ambulatory ECG recorder (ECG holter) which can continuously record one, two or three channels for a period up to several days (11 days on 1 channel, 6 days on 2 channels, 4 days on 3 channels).
The entire ECG is stored on a removable memory (compact falsh card) and can be read directly by HolterSoft Ultima software installed in a computer.
The VISTA PLUS has a microphone allowing the recording of voice messages from the physician or the patient (patient diary) during monitoring.
This ECG holter recorder does not perform any analysis on the ECG data.
The VISTA PLUS recorder weighs about 100gr. including flash card and batteries and is connected to the patient with a single multilead cable connected to the ECG electrodes.
The VISTA PLUS is supplied in a case containing a 128 MB compact flash memory card, one standard ECG cable 180cm, two neck protective pouches, one protective pouch for belt, one belt, one shoulder strap, two 1,5V AAA batteries, and a CD-Rom which contains multilingual user's manual.

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Intended use :

VISTA PLUS and HOLTERSOFT ULTIMA INTENDED USE

Recorder :

Vista Plus is intended to record one, two or three channels surface ECG data from ambulatory patients (Holter) for period up to 11 days on one channel, 6 days on two channels, 4 days on three channels. Recorded data are intended to be analysed by holterSoft Ultima analysis on the ECG data.

Software :

HolterSoft Ultima is intended to read data acquired by the Vista Plus, analyze, edit, review, report and store these data. The system is intended to be used by trained operators under the direct supervision of a licensed Health Care practitioner in a hospital or a clinic environment.

The Heart Rate Variability (HRV) Option of HolterSoft Ultima is intended to be used for the analysis of the variability in RR intervals (heart rate) and to report measurements of the variability of Heart Rate data.
HRV option is intended to provide only HRV measurements and is not intended to produce any interpretation of these measurements or any kind of diagnosis
The HRV measurements produces by HRV option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.
The HRV feature of this device has not been shown to be safe and effective for a specific clinical diagnosis.

The Obstructive Sleep Apnoea Syndrome option is intended to be used for a specific analysis of the Variability of the Increment of the RR Intervals and to report the resulting measurements.
OSAS option is intended to provide only measurements and is not intended to produce any interpretation of these measurements or any kind of diagnosis
The OSAS measurements produces by HRV option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.

The QT option of HolterSoft Ultima is intended to be used for analysis each ECG channel separately for obtaining the measurements of the QT Interval and the T wave.
QT option is intended to provide only QT Interval and T wave measurements and is not intended to produce any interpretation of these measurements or any kind of diagnosis
The measurements produces by QT option are intended to be used by qualified personnel in evaluating the patient in conjunction with patient's clinical history, symptoms, other diagnostic tests, as well as the professional's clinical judgement.
The QT option is intended to be used for adult patients only

Comparison of technology characteristics to predicate devices :

RECORDERS :

Predicate devices :

- Spiderview - ELA Medical - K032466
- Cardio Id+ (RZ153+) - ROZINN ELECTRONICS – K022540
- Digitrak Plus – BRAEMAR (commercialisé par ZYMED/PHILIPS) – K993617

Specification	Vista Plus	Spiderview	Cardio Id+ (RZ153+)	Digitrak Plus
	Novacor	ELA Medical	Rozinn	Braemar
Type	Digital	Digital	Digital	Digital
Number of channels	1, 2, 3	2, 3, 5, 9	2, 3, 12 (option)	2, 3
Recording duration	Up to :264 h	Up to 96 h	Up to 48 h	Up to 120 h
Sampling rate	200 Hz	200 Hz	1024 Hz	175 Hz
Resolution	10 bits	15 bits	12 bits	10 bits
Dynamic range	+/- 6 mV	+/- 16 mV	+/- 6, +/-3 or	

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			+/- 1,5 mV	
Bit resolution	12 µV	10 µV	1,465 µV	
Compression	No	Yes	No	No
Analogue Bandwidth		0,05-25 Hz in standard mode; 0,05-80 Hz in no compression mode	0,05-75 Hz	0,05-60Hz
Pacemaker spike detection and reporting	Yes	Yes	Yes	Yes
Open lead detection	Yes	Yes	Yes	Yes
Impedance test	Yes	Yes	Yes	Yes
Storage capacity	Up to 512 MB	Up to 64 MB	Up to 512 MB	
Memory type	CF card	MMC or SD flash card	CF card	Internal Flash memory (non removable)
LCD	Yes	Yes	Yes	Yes
Keyboard	Yes	Yes	Yes	Yes
Size	86x54x19	97x54x23 mm	108x79x22 mm	85x65x20 mm
Weight	100g	110g	145 g	100 g
Cables	5 wires	3, 5, 7 wires	5, 7 wires	5 wires
Accessories	Belt, shoulder strap, pouch, neck pouch	Belt + pouch	Belt + pouch	Belt + pouch
Batteries	2 AAA (1,5 V)	1 AA (1,5 V)	1 or 2 AA (1,5 V)	1 AA (1,5 V)°
Rechargeable batteries	Accepted	Accepted	Accepted	Accepted
Patient ID record	Vocal message	With the display + keyboard	With the display + keyboard	With the display + keyboard
ECG display	At any time (programmable)	Preview only	Preview only	Preview only
Real-type built in analysis	Yes, for real-time HR calculation	No	No	No
Event marker	Yes (event key + vocal message)	Yes	Yes	Yes
Display during recording				
Time	programmable	Yes (during hook up inly)	Yes	Yes
HR	programmable	No	No	No
HR curve	programmable	No	No	No
ECG analysis	Analysis software on PC	Analysis software on PC	Analysis software on PC	Analysis software on PC
Replay and analysis system	HolterSoft Ultima	Syneview/Synescope	Holter for Windows	Philips 1810 series or 2010 software

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SOFTWARE :

Predicate devices for HolterSoft Ultima:

- Synetec, ELA Medical – K002817
- 2010 PLUS Holter for Windows, AGILENT/PHILIPS – K010949
- MARS Unity, MARQUETTE/GE – K991786

Specifications	HolterSoft Ultima	Synetec	2010 plus Holter	Mars Unity
	Novacor	ELA Medical	Agilent	Marquette
Type	Software	Software	Software	Workstation
PC based	Yes	Yes	Yes	Yes
OS compatibility	Windows 98,NT,2000, XP	Windows 98/NT/2000/XP	Windows 98, NT,2000,XP	NA
Input data	Digital (CF card from Vista series recorders)	Digital (PCMCIA flashcards from Syneflad/MMC or SM cards from Spiderview) and tape	Digital (USB transfer from Zymed Digitrak Plus recorder)	Digital (USB transfer from the "Seer Light" interface) and tape
Graphic User Interface	Yes	Yes	Yes	Yes
Templates (shapes) edition	Yes	Yes	Yes	Yes
Events list display	Yes	Yes	Yes	No
Arrhythmia detection	Yes	Yes	Yes	Yes
Conduction abnormalities detection	Yes	Yes	Yes	Yes
ST segment	multichannel	multichannel	multichannel	multichannel
Superimposition	Yes	Yes	Yes	Yes
PM patient analysis	Yes	Yes	Yes	Yes
Report customisation	Yes	Yes	Yes	Yes
Report edition	Yes	Yes	Yes	Yes
ECG strip edition and printing	Yes	Yes	Yes	Yes
Archiving	Yes	Yes	Yes	Yes
Report Export	Yes	No	No	No
AFib	Yes	No	No	No
Events Histograms/trends	Yes	Yes	?	Yes
RR histrogram	Yes	Yes	Yes	Yes
Editing/Printing full disclosure	Yes	Yes	Yes	Yes
Editing tools for QRS insertion/suppression	Yes	Yes	?	Yes
Time domain HRV	Yes	Yes	Yes	Yes
Frequency Domain HRV	Yes	Yes	Yes	Yes
QT	Yes	Yes (but not commercially available in the US)	Yes	Yes

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OSAS	Yes	No	No	No
Networking	Yes	Yes	Y	Yes
Patient Diary	Voice Messages	No	No	Text Input

Predicate devices for HolterSoft Ultima Atrial Fibrillation Module :

King of Heart Express + AF K, CARD GUARD/INSTROMEDIX, K020825

Device	HolterSoft Ultima AF module	King of Heart Express + AF
Type of data recorded	Continuous ECG	ECG strips
Sampling rate	200 Hz	218 Hz
Bit resolution	10 µV	15,6 µV
Monitoring duration	264 hours	7 days
Recording duration	264 hours	10 minutes
Maximum number of events	No limit	60
Maximum event length	264 hours	10 minutes
Number of channels used for the analysis	1 to 3	1

Conclusion :

The information presented in this submission provides reasonable assurance that the VISTA PLUS Holter ECG recorder will perform in a safe and effective manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2005

Novacor
c/o Mr. Dominique Grenier
Regulatory Affairs Officer
4 Passage Saint Antoine
92508 Rueil Malmaison
Cedex
FRANCE

Re: K042108
Trade Name: Vista Plus
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: MLO
Dated: December 23, 2004
Received: December 29, 2004

Dear Mr. Grenier:

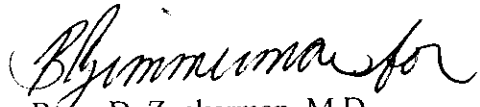
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042108/S2

Indications for Use

510(k) Number (if known): K042108

Device Name: **VISTA PLUS**

Indications For Use:

Recorder :

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Software :

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042108

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
